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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,814

03/28/2007

Raz Jelinek

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EXAMINER

SINGH, SATYENDRA K

ART UNIT

PAPER NUMBER

1657

MAIL DATE

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12/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,814	Applicant(s) JELINEK, RAZ	
	Examiner SATYENDRA K. SINGH	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 7-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/28/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response (and claim amendments) filed on 09/30/2009 is duly acknowledged.

Claims 1-30 are currently pending in this application.

Election/Restrictions

Applicant's election **without traverse** of group I (claims 1-6; directed to "**isolated cells comprising nanopatch sensors integrated into the cell membrane thereof**", as recited in claim 1) in the reply filed on 9/30/2009 is acknowledged.

Claims 7-30 (non-elected inventions of groups II-VI) are withdrawn from further consideration.

Claims 1-6 (elected invention of group I) are examined on their merits in this office action.

Information Disclosure Statement

The information disclosure statement filed on 03/28/2006 is duly acknowledged. However, it fails to fully comply with 37 CFR 1.98(a)(2), which requires **a legible copy of each cited foreign patent** document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Applicants are advised to provide copies of WIPO documents (WO 00/1819 and WO 95/27204) listed on the IDS citation.

Claim Objections

1. Claim 4 is objected to because of the following informalities: claim 4 recites the limitation of “**10, 12-tricosadionic acid**”, which is incorrect and should be amended to recite “**10, 12-tricosadiynoic acid**” (see instant disclosure, page 16, 3rd paragraph, in particular). Appropriate correction is required.
2. Claim 6 is objected to because of the following informalities: claim 6 has a “\” after the period, which is inappropriate. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation “(I)solated cells comprising nanopatch sensors **integrated** into the cell membrane thereof, wherein said sensors are provided in the form of perturbation-sensitive constructs...”, which is ambiguous and confusing. Since, the term has not been explicitly defined, and the claims do not provide as to how said nanopatch sensors are integrated into the cell membrane (i.e. non-covalently, covalently, hydrophobic interactions, incorporation by means of cellular biosynthesis, etc. to name a few ways of “integration”), and whether said “isolated cells” are viable or non-viable, it is unclear as to what exactly is being encompassed by the claim recitation. Appropriate explanation/correction is required.

Since, claims 2-6 depend from the broader claim 1, they are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by JOHNSTON et al (1980; [U]).

Claims are directed to “**Isolated cells** comprising nanopatch sensors **integrated** into the cell membrane thereof, wherein said sensors are provided in the form of perturbation-sensitive constructs, and wherein said perturbation-sensitive constructs respond to perturbations of the cell membrane by means of a detectable change in one or more physical or chemical properties associated with said construct; the isolated cells according to claim 1, wherein the perturbation-sensitive construct comprises a polymer associated with one or more lipid components; the isolated cells according to claim 2, wherein the polymer is polydiacetylene (PDA); the isolated cells according to claim 3, wherein the PDA is a polymer of **10,12-tricosadiynoic acid**, and the lipid components are selected from the group consisting of dimyristoylphosphatidylglycerol, dimyristoylphosphatidylcholine and dimyristoylphosphatidylethanolamine; the isolated cells according to claim 1, wherein the detectable change in the physical or chemical properties associated with the perturbation-sensitive constructs is a change in the visible range absorption spectrum of said cells; and the isolated cells according to claim 1, wherein the detectable change in the physical or chemical properties associated with the perturbation-sensitive constructs is a change in the fluorescent emission spectrum of said cells.”

Johnston et al [U] disclose isolated, *Acholeplasma laidlawii* A cells comprising nanopatch sensors integrated (by UV-irradiation, using Mineralight R52 lamp) into the cell membrane thereof (i.e. cells grown on diacetylenic fatty acids; see summary on

page 57, “Scheme I” on page 60, and Table I on page 61, in particular), wherein said sensors are provided in the form of perturbation-sensitive constructs, and wherein said perturbation-sensitive constructs respond to perturbations of the cell membrane by means of a detectable change in one or more physical or chemical properties associated with said construct; wherein the perturbation-sensitive construct comprises a polymer, polydiacetylene associated with one or more phospholipid components, wherein the PDA is a polymer of 10,12-tricosadiynoic acid, and the phospholipid component such as dimyristoylphosphatidylcholine (see pages 59-61; section “Synthesis of diacetylenic acids”, “Scheme I” on page 60; and Table I on page 61, “Diacetylenic phospholipids”, in particular); wherein the detectable change in the physical or chemical properties associated with the perturbation-sensitive constructs is a change in the visible range absorption spectrum, or a change in the fluorescent emission spectrum of said cells (taken as inherent physico-chemical property of the constructs integrated into cell membrane; which are disclosed by the prior art; see figures 1-4, and page 67, 1st and last paragraphs, in particular).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claim 1 of copending Application No. 11/666,134 (same inventor). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 in the copending application is also directed to "*A construct comprising functional membrane fragments and one or more perturbation-detecting polymers associated therewith, wherein said construct responds to perturbations of said membrane fragments by means of a detectable change in one or more physical or chemical properties associated with said construct*", which is deemed generic to the claimed invention in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

NO claims are allowed.

Pertinent Prior Art:

1. ALONSO A. et al. (Form 892 [V])- Polymerisation of diacetylene fatty acid in cultures of *Bacillus cereus*, *Biochimica et Biophysica Acta*, 1982, volume 712, pages 292-298.
2. LEAVER J. et al. (Form 892 [W])- The biosynthetic incorporation of diacetylene fatty acids into the biomembrane of *Acholeplasma laidlawii* A cells and polymerisation of the biomembranes by irradiation with ultraviolet light, *Biochimica et Biophysica Acta*, 1983, volume 727, pages 327-335.
3. JELINEK R. et al. (Form 892 [X])- Interfacial catalysis by phospholipases at conjugated lipid vesicles: colorimetric detection and NMR spectroscopy, *Chemistry & Biology*, November 1998, volume 5, No. 11, pages 619-629.
4. RIBI (US 5,156,810; [A])- Biosensors employing electrical, optical and mechanical signals (see column 12, 4rth paragraph, in particular).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Satyendra K. Singh/
Examiner, Art Unit 1657

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